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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,260	06/20/2005	Laurence Paris	2004-219	8662

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2000 MARKET STREET
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PHILADELPHIA, PA 19103

EXAMINER	
BERRIOS, JENNIFER A	

ART UNIT	PAPER NUMBER
1619	

NOTIFICATION DATE	DELIVERY MODE
06/30/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/511,260	PARIS, LAURENCE	
	Examiner	Art Unit	
	Jennifer A. Berríos	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *79-108* is/are pending in the application.

4a) Of the above claim(s) *89 and 97-104* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *79-88,90-96 and 105-108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10/14/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/12/2004 and 10/14/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group IV, claims 79-108 in the reply filed on 9/29/2009 is acknowledged. The traversal is on the ground(s) that US Patent 6,503,955 does not disclose or suggest the special technical feature of the presently claimed invention. This is not found persuasive because as it can be seen in the rejections below, the groups do in fact lack a special technical feature.

2. Applicant further traverse the species requirement on pages 4-5 of the response filed 9/29/2009, however these arguments are not persuasive. In order to require a species election in a 371 application, Examiner must demonstrate that the species lack a special technical feature amongst each other, which was demonstrated in the restriction requirement mailed 4/30/2009 and in the rejections found below.

3. Applicant elected:

   a. Synthetic polymer;

   b. Cellulose;

   c. Copolymers of acrylic acid;

   d. Solid; and

   e. Hydrophilic additive class.

   The requirement is still deemed proper and is therefore made FINAL.

4. Claims 89 and 97-104 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/29/2009.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 83 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 83 recites the limitation, "derivative of …" in reference to the instantly claimed compounds and their "derivatives." Applicant has not described the claimed genus of "derivatives" in a manner that would indicate they were in possession of the full scope of this genus, or even to describe what this genus is comprised of.

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP §2163. In particular, Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plain for obtaining the claimed chemical invention." Eli Lilly, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.1 "Written Description" Requirement

("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter aria*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed. Reg. at 1106 (emphasis added)). Moreover, although Eli Lilly and Enzo were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. Univ. of Rochester v. G.D. Searle & Co., 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

In the instant case, the claims are drawn to derivatives of acrylic acid or of acrylamide polymers. The claimed "derivatives of…" encompass any compound that contains the identical core as the instantly claimed compound, with a differing of substituents quoted for the identical purpose. Applicants describe no "derivatives of…" in the specification. No derivatives are described adequately enough to allow one skilled in the art to ascertain that Applicant is in possession of the entire scope of the claimed genus. Applicants have not described this genus in a manner that would allow one skilled in the art to immediately envisage the compounds contemplated for use. As such, the claims lack adequate written description for the myriad of compounds embraced by the claimed "derivatives thereof."

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984)

(affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 79-87, 90, 92-96 and 105-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dobrozsi et al (US 6,503,955, filed 9/11/2000) and Caramella et al (US 6,355,272, pub. date: 3/12/2002).

Dobrozsi teaches pourable liquid vehicles comprising a) 26%-100% polyoxyalkylene block copolymer, b) 0-70% glycol and 0-50% water.

Regarding claim 85: Said vehicles have a viscosity value of less than or equal to 7 pascal-seconds, which is equivalent to less than or equal to 7000 millipascals.

Regarding claim 1, 83-84, 86 and 108: Example XI demonstrates a composition comprising Promethazine HCL, an antihistamine antiemetic, which can be considered an active ingredient belonging to the therapeutic class, in an amount of .25%. The composition further comprises Carbomer (a copolymer of acrylic acid, as defined by the instant specification and claims to be a liquid matrix ingredient of the inverted class) in amounts of 1.0%.

Regarding claims 86: The active agent is milled to reduce its particle size, thus being in a solid state and is mixed with the poloxamer Pluronic L62, present in amounts of 98.75%, which can be considered an organic solvent. The poloxamer has both a hydrophilic and a hydrophobic segment (Col. 6, lines 8-9).

Regarding claim 90: Although Dobrozsi doesn't specify if the active agent is a coated or uncoated powder, both are acceptable as recited by the instant claims. Therefore the powder of Dobrozsi satisfies the instant claims, as one of skill in the art would recognize that a powder is either coated or uncoated.

Regarding claims 106 and 107: Example XIX demonstrates a pourable liquid vehicle of Dobozski which is filled into hard gelatin capsules or soft elastic gelatin capsules to provide controlled release of the active agent.

Regarding claims 81: After the gelatin capsule is swallowed, the shell dissolved in the gastrointestinal tract and the liquid fill immediately transforms into a slow dissolving gel that provides controlled release of the active agent.

Dobrozsi does not teach the at least one ingredient modulating the release of the active agent to be a polysaccharide as recited by instant claim 92-94. Dobrozsi also does not teach the limitations recited by instant claims 91 and 95-96.

Regarding claim 91-94 and 96: Caramella teaches a complex between carrageenan and a water-soluble drug in powder form having an average particle size between 10 and 100 micrometers (Abs). This complex can be used to create controlled release pharmaceutical compositions.

Suitable water-soluble drugs include promethaxine HCL (Col. 4, lines 18-19).

Regarding claim 95: Controlled release composition contains the complex in amounts ranging from 60-100%. Example 1 demonstrates a complex containing carrageenan (43.86%) And promethazine HCL (56.14%), thus overlapping with the instantly claimed ranges.

The complex can be used in the preparation of solid oral dosage forms tablets, pellets and granules. Said pellets and granules can be contained in hard or soft capsules (Col. 4, lines 57-61).

Regarding claim 105: The employment of small particle size fractions reduces the release rate to values that are suitable for once a day administration, meaning a release completed within 20-24hrs (Col. 4, lines 64-67 to Col. 5, line 1).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Dobrozsi and Caramella. One

of skill in the art would have been motivated to include the complex (carrageenan and an active agent, such as promethazine HCL) into the pourable liquid vehicle of Dobrozsi, in order to create a capsule pharmaceutical composition suitable for once a day administration having a completed release between 20-24hrs. One of skill in the art would expect reasonable success as both Dobrozsi and Caramella teaches controlled release pharmaceutical compositions, having an active agent in particle form, which can be in the form of soft or hard capsules.

Regarding claims 80 and 82: As the combination of the prior art references teach all the structural limitations of the claims in amounts overlapping with those amounts instantly claims, the composition taught by the prior art and the composition of the instant claims are expected to have the same properties, absent evidence to the contrary.

9. Claim 107 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dobrozsi et al (US 6,503,955, filed 9/11/2000) and Caramella et al (US 6,355,272, pub. date: 3/12/2002) as applied to claims 79-87, 90, 92-96 and 105-108 above, and further in view of Cole et al (Int. Journal of Pharmaceutics, Vol. 231, January 2002, pages 83-95.

Dobrozsi and Caramella teach all the limitations of instant claims 79-87, 90, 92-96 and 105-108, but do not teach the capsule to be made of hydroxypropylmethylcellulose (HPMC), as elected.

Cole teaches enteric coated HPMC capsules designed to achieve intestinal targeting, which provide a good adhesion, which facilitates coating the capsules with enteric polymer coatings (Abs).

The most commonly used material for manufacturing capsules is gelatin. Although it is possible to coat hard gelatin capsules, the process is at best very sensitive, especially if an aqueous coating system is used, and can lead to shell embrittlement and poor adhesion of the coat to the smooth gelatin surface. A pre-coating can reduce interactions between the gelatin and the enteric polymer but is time consuming and complicated.

HPMC capsules have been available commercially, mainly to the dietary supplement industry as a vegetarian alternative to gelatin, for approximately 10 years. As HPMC is often used as a pre-coating material for enteric coated tablets, it may be expected that the application of enteric type polymers to a capsule made from HPMC would result in 'good polymer to polymer' adhesion and compatibility (Pg 85).

A procedure recommended for coating gelatin capsules also involved pre-coating with Eudragit® L 30 D-55 plasticized with glycerol to improve adhesion and storage stability. When the capsule itself is made of a cellulose derivative it would be expected, based on the experience with enteric coating of tablets with a pre-coating of HPMC, that a pre-coating step could be eliminated. Gelatin capsules have a very glossy surface due to the fact that the amount of regular reflection from the surface is high and the amount of diffuse reflection is low. In contrast, HPMC capsules have a visually matt surface with a greater amount of diffuse reflection, suggesting a more irregular surface. During the coating process the temperature of the capsule bed reaches 25–27 °C. At this

temperature HPMC is soluble and will start to dissolve in the aqueous based film providing a strongly adhesive surface. Gelatin, on the other hand, is only slightly soluble at this temperature and its surface characteristics will remain virtually unchanged (Pg 87).

Enteric coated HPMC capsules can thus be considered to provide a good container for drugs during the early development phase providing the possibility of drug release either in the small intestine or towards the colon (Pg 94).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Dobrozsi/Caramella and Cole. Based on the teachings of Cole one of skill in the art would have recognized that the material, with which the capsule of Dobrozsi was made, could be changed depending on the type of pharmaceutical composition desired. One of skill in the art would recognize that HPMC capsules have certain advantages over gelatin capsules for use in pharmaceutical capsules having an enteric polymer coating, due to enhanced adhesion and are prepared in a simpler, easier way. Finally one of skill in the art would have a reasonable expectation of success absent evidence to the contrary.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Berríos whose telephone number is

(571)270-7679. The examiner can normally be reached on Monday-Thursday: 7:00am-4:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 270-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer A Berríos/
Examiner, Art Unit 1619

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635